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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/817,704	08/25/1997	ANTHONIUS J. SWAAK	P8214-7002	8580

7590

04/04/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/817,704

Applicant(s)
Swaak

Examiner
G.R. Ewoldt

Art Unit
1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 28, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 20, 23-26, and 31-35 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 23-26, and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 18, 20, 23-26, and 31-35 are currently pending in this application.
2. Applicant's request for reconsideration, filed 1/28/03, is acknowledged. In view of Applicant's submission demonstrating that the Swaak et al. reference was published less than 1 year prior to the instant application's international filing date, the rejection under 35 U.S.C. 102(b) has been withdrawn.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:
A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
5. Claims 18, 20, 23-26, and newly added Claims 32-33, stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Toshihide et al. (of record), for the reasons of record as set forth in Papers No. 27, 30, and 35, mailed 5/21/01, 1/25/02, and 9/30/02, respectively.

Applicant arguments, filed 1/28/03, have been fully considered but are not found persuasive. Applicant argues that "Toshihide et al. disclose the use of EPO during 2 or 3 weeks for increasing erythropoiesis in RA patients."

It is the Examiner's position that this admission that the claimed method was performed on at least a subpopulation of the patients of the instant claims (RA patients) appears to be an admission that the rejection is proper.

Applicant continues, however, with an argument that "However, it is disclosed that during this treatment period 800 or 1200 ml of blood was collected from said patients; this step is not performed in the presently claimed method. Hence, there is a clear difference between the present claims and the method disclosed in Toshihide et al."

It is the Examiner's position that the instant claims recite no limitation that would exclude the collection of blood, indeed, the use of the term "comprising" in the claimed method indicates that the claimed method encompasses any method comprising any additional steps.

Applicant argues that "Furthermore, the substantial removal of blood leads to less EPO being available for the treatment of RA disease symptoms. Hence, Applicants are of the opinion that due to the blood removal (and as a consequence: lower available EPO levels), the patients described in Toshihide et al. are not inherently treated for RA disease symptoms."

This argument comprises merely an unsubstantiated assertion of an attorney. An attorney's argument, however, is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. Additionally, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration MPEP 2145. Accordingly, the rejection is proper.

6. Claims 18, 20, 23-26, 31, and newly added Claims 32-33, stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pettersson et al. (of record), for the reasons of record as set forth in Papers No. 27 and 30, mailed 5/21/01 and 1/25/02, respectively.

Applicant arguments, filed 1/28/03, have been fully considered but are not found persuasive. Applicant argues that "The present invention relates to the new use of EPO for

alleviating the disease activity of chronic inflammation in general and rheumatoid arthritis in particular," and "Pettersson et al. describe a 24-week open clinical study in which 12 patients with RA and anemia were treated with EPO."

Again, it is the Examiner's position that this admission that the claimed method was performed on RA patients seems to be an admission that the rejection is proper.

Applicant continues, however, with an argument that because Pettersson et al. also teaches a method that includes oral iron supplementation, the method of the instant claims is patentably distinct, "because Pettersson et al. do not suggest omitting the supplementation of iron, the claims are clearly inventive. The claims are therefore novel and would not have been obvious over Pettersson et al."

It is the Examiner's position that the instant claims again recite no limitation that would exclude oral iron supplementation, indeed, the use of the term "comprising" in the claimed method indicates that the claimed method encompasses any method comprising any additional steps or supplemental reagents. Accordingly, the rejection is proper.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 34 and 35 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, a method wherein "the treatment period is 3 to 6 weeks", for the reasons of record as set forth in Paper No. 35, mailed 9/30/02.

Applicant arguments, filed 1/28/03, have been fully considered but are not found persuasive. Applicant argues that the recited time period on which the rejection is based, 3 to 6 weeks is supported by the specification at pages 6 and 10. Applicant further argues that the Office previously agreed that there was support for the limitation.

Regarding the disclosure, at page 6 the specification discloses a time of 6 weeks. At page 10 the specification discloses a time range of from 0 to 6 weeks. Neither of these disclosures can support a recitation of an intermediate time period of 3 to 6 weeks. In this instance the 6 week disclosure can be considered to be a species whereas the 0 to 6 week range can be considered to be a genus. Applicant has claimed a time period that can be considered to be a sub-genus, i.e., 3 to 6 weeks. Neither the disclosed species nor the disclosed genus is sufficient to support the claimed sub-genus.

Regarding the assertion that the Office previously agreed that there was support for the limitation, Applicant is advised that each application is examined by the Examiner of record and that the Examiner of record cannot agree to the instant limitation.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful,

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the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).

A handwritten signature in dark ink, appearing to read 'G.R. Ewoldt', with a stylized flourish at the end.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
April 3, 2003